

K 013463

Special 510(k)

Summary of Safety and Effectiveness

ArthroCare Corporation

ArthroCare ArthroWands®

ENTec® EVac™ Plasma Wand™

NOV 15 2001

Manufacturer: ArthroCare, Corporation
595 North Pastoria Avenue
Sunnyvale, CA 94085-2936

Establishment Registration Number: 2951580

Contact Person: Bruce Prothro
Vice President, Regulatory Affairs,
Quality Assurance, and Clinical
Research

Date Prepared: October 17, 2001

Device Description

Classification Name: Electrosurgical Cutting and Coagulation
Device and Accessories (21 CFR
878.4400)

Trade Name: ArthroCare ArthroWands®
ENTec® EVac™ Plasma Wand™

Generic/Common Name: Electrosurgical Device and Accessories

Predicate Devices

ArthroCare ArthroWands	K011083
ENTec EVac Plasma Wand	K011279

Intended Use

ArthroCare ArthroWands

- The ArthroCare ArthroWands are indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures:

Arthroscopic and Orthopedic Procedures	Joint Specific or All Joints (ankle, elbow, hip, knee, shoulder, and wrist)
<i>Ablation and Debridement</i>	
• ACL/PCL	Knee
• Acromioplasty	Shoulder
• Articular Cartilage	All Joints
• Bursectomy	All Joints
• Chondroplasty	All Joints
• Facia	All Joints
• Ligament	All Joints
• Notchplasty	Knee
• Scar Tissue	All Joints
• Soft Tissue	All Joints
• Subacromial Decompression	Shoulder
• Synovectomy	All Joints
• Tendon	All Joints
<i>Excision and Resection</i>	
• Acetabular Labrum	Hip
• Articular Labrum	All Joints
• Capsule	All Joints
• Capsular Release	Knee
• Cartilage Flaps	Knee
• Cysts	All Joints
• Discoid Meniscus	Knee
• Frozen Shoulder Release	Shoulder
• Glenoidale Labrum	Shoulder
• Lateral Release	Knee
• Ligament	All Joints
• Loose Bodies	All Joints
• Meniscal Cystectomy	Knee
• Meniscectomy	Knee
• Plica Removal	All Joints
• Scar Tissue	All Joints
• Soft Tissue	All Joints
• Synovial Membrane	All Joints
• Tendon	All Joints
• Triangular Fibrocartilage (TFCC)	Wrist
• Villusctomy	Knee
<i>Coagulation</i>	
• ACL/PCL	Knee
• Articular Cartilage	All Joints
• Carpal Ligaments	Wrist
• Glenohumeral Capsule	Shoulder
• Ligament	All Joints

• Medial Retinaculum	Knee
• Rotator Cuff	Shoulder
• Tendon	All Joints
• Wrist Tendons	Wrist

ENTec EVac Plasma Wand

- The ENTec EVac Plasma Wand is indicated for ablation, coagulation, and hemostasis of soft tissue in tonsillectomy and adenoidectomy procedures.

Product Description

The Wands are bipolar, single use, high frequency electrosurgical devices designed for specific indications.

Substantial Equivalence

This Special 510(k) proposes a modification in performance specifications and materials for the Wands, which were previously cleared under K011083 and K011279 on June 28, 2001 and July 19, 2001, respectively. The indications for use, technology, principle of operation, dimensional specifications, packaging, labeling, and sterilization parameters of the Wands remain the same as in the predicate cleared 510(k)s.

Summary of Safety and Effectiveness

The modified Wands, as described in this submission, are substantially equivalent to the predicate devices. The proposed modification in performance specifications and materials are not substantial changes or modifications, and do not significantly affect the safety or efficacy of the devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Bruce Prothro
Vice President, Regulatory Affairs,
Quality Assurance, and Clinical Research
ArthroCare Corporation
595 North Pastoria Avenue
Sunnyvale, California 94085-2936

NOV 15 2001

Re: K013463

Trade/Device Name: ArthroCare ArthroWands®, ENTec® Evac™ Plasma Wand™
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: October 17, 2001
Received: October 18, 2001

Dear Mr. Prothro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


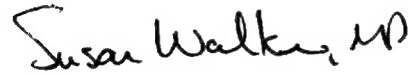
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 15 2001

Indications Statement

Device Name: ArthroCare ArthroWands®
ENTec® EVac™ Plasma Wand™

510(k) Number: K 013463

Indications for use:

ArthroCare ArthroWands

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ENTec EVac Plasma Wand

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use
(Per 21 CFR 801.109)

Susan Wall
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013463